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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,344	07/08/2003	Linda D. Artman	1950-7467.1US(N-405US-DIV	7848

7590 09/13/2006

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EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/614,344	ARTMAN ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/19/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

Applicant's arguments filed April 21, 2006 have been fully considered but they are not persuasive. The previous Office Action dated 12/21/2005 rejects claim 37 over Balandrin et al. (U.S. Patent 5,506,268) in view of Drug Facts and Comparisons 1999 ed. Pages 1595-1597 ("Drug Facts"). Applicants argue that the cited references do not

teach or suggest all of the claim limitations, do not provide a reasonable expectation of success and do not provide a motivation to produce the claimed invention. This is not persuasive because claim 37 is drawn to a method of treating a convulsive disorder comprising administration of isovaleramide to a patient. The combination of the two references is obvious because isovaleramide is taught as an anxiolytic or sedative agent in the Balandrin et al. reference (Col. 5, lines 46-48) and Drug Facts teaches that another well-known anxiolytic, diazepam, is used as an anticonvulsant in status epilepticus and recurrent convulsive seizures. The Drug Facts reference shows that treating such conditions as anxiety disorders and convulsive disorders such as status epilepticus, one having ordinary skill in the art would view these conditions as art equivalents. Therefore, reasonable expectation of success to treat convulsive disorders, such as status epilepticus, with the anxiolytic isovaleramide would be expected because anxiety and convulsive disorder, such as status epilepticus are art equivalent conditions and other anxiolytics, such as diazepam, have been used to treat status epilepticus.

Claim 39 was also rejected in the same Office Action over Balandrin et al. in view of Pharmacotherapy, A Pathophysiologic Approach, (Dipiro et al. 2nd ed. Elsvier, 1991, pages 1232, 1238) ("Pharmacotherapy"). Applicant's argue that the cited references do not teach or suggest all of the claim limitations and do not provide a motivation to combine to produce the claimed invention. This is not persuasive because claim 39 is drawn to a method of treating headaches with isovaleramide to a patient. Balandrin et al. teach isovaleramide as an anxiolytic as discussed above. Balandrin et al. also teach

that isovaleramide is useful in treating such conditions as tension, premenstrual syndrome, and hyperexcitability in children (Col. 7, lines 19-30). The Pharmacotherapy reference is used to indicate that headache is a symptom associated with premenstrual syndrome (see Table 72.1). It would have been obvious to one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that isovaleramide would treat headache because Balandrin et al. teach that isovaleramide is effective in treating premenstrual syndrome which includes headache.

In view of the above, the Office Action of December 21, 2005 is deemed proper and asserted with full force and effect herein to obviate applicant's claims.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 37 rejected under 35 U.S.C. 103(a) as being unpatentable over Balandrin et al. (U.S. Patent 5,506,268) in view of Drug Facts and Comparisons 1999 ed. Pages 1595-1597 ("Drug Facts").

Balandrin et al. teach isovaleramide as an effective anxiolytic agent (Col. 5, lines 46-49). Balandrin et al. also teach that isovaleramide decreases spontaneous locomotor activity (Col. 10, lines 2-14).

Balandrin et al. does not teach the use of isovaleramide for convulsive disorders selected from the group consisting of simple partial seizures, complex partial seizures, generalized tonic-clonic seizures, secondarily generalized seizures, status epilepticus, and trauma-induced seizures.

Drug Facts teaches that diazepam is an anxiolytic that is a muscle relaxant and an anti-convulsant to treat status epilepticus and recurrent convulsive seizures (p. 1595).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize isovaleramide as a treatment for convulsive disorders such as status epilepticus because the teachings of Drug Facts shows that an effective anxiolytic, diazepam, is useful as a muscle relaxant and an anti-convulsant to treat status epilepticus. One having ordinary skill in the art would have been motivated to use isovaleramide as a treatment for convulsive disorders, including status epilepticus, because another anxiolytic (diazepam) has been used as a muscle relaxant and an anti-convulsant.

Claim 39 rejected under 35 U.S.C. 103(a) as being unpatentable over Balandrin et al. in view of Pharmacotherapy, A Pathophysiologic Approach, (Dipiro et al. 2nd ed. Elsvier, 1991, pages 1232, 1238) ("Pharmacotherapy").

Balandrin et al. teach isovaleramide as an anxiolytic as discussed above. Balandrin et al. also teach other conditions that benefit from treatment with

isovaleramide, including tension, restlessness, and premenstrual syndrome (Col. 7, lines 19-30).

Balandrin et al. do not disclose that isovaleramide treats headache.

Pharmacotherapy teaches that headache is a common symptom associated with premenstrual syndrome (see Table 72.1). It is also taught that a known anxiolytic agent, alprazolam, is useful in treating premenstrual symptoms (p. 1238, 2nd paragraph, left column).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to treat headaches with isovaleramide because Balandrin et al. teach that isovaleramide treats tension, restlessness and premenstrual syndrome, of which headache is a common symptom of the latter as taught by Pharmacotherapy. One having ordinary skill in the art at the time the invention was made would have been motivated to treat headache with isovaleramide, because anxiolytic agents have effectively been used to treat premenstrual symptoms, including headache.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER